

Legend: (Proposed Amendments)

Single Underline = Proposed new language

[Bold, Print, and Brackets] = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

§289.251. Exemptions, General Licenses, and General License Acknowledgements.

(a) (No change.)

(b) Scope. Except as otherwise authorized, no person shall receive, possess, use, transfer, own, or acquire radioactive material except as authorized in a general license or general license acknowledgement issued in accordance with this section, or in a specific license issued in accordance with §289.252 of this title (relating to Licensing of Radioactive Material), **[§289.254 of this title (relating to Licensing of Radioactive Waste Processing and Storage Facilities),]** §289.255 of this title (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography), §289.256 of this title (relating to Medical and Veterinary Use of Radioactive Material), §289.258 of this title (relating to Licensing and Radiation Safety Requirements for Irradiators), or §289.259 of this title (relating to Licensing of Naturally Occurring Radioactive Material (NORM))**[, or §289.260 of this title (relating to Licensing of Uranium Recovery and Byproduct Material Disposal Facilities)].**

(c) - (d) (No change.)

(e) Exemptions for radioactive material other than source material.

(1) Exempt concentrations.

(A) - (B) (No change.)

(C) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license, as specified in §289.252 of this title, if the manufacturer, processor, or producer transfers radioactive material contained in a product or material that does not exceed the concentrations specified in subsection (1)(1) of this section, and that has been introduced into the product or material by a licensee holding a specific license issued by the NRC, any agreement state, or any licensing state that expressly authorizes such introduction. The exemption specified in this subparagraph does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(2) Exempt quantities.

(A) Except as provided in subparagraphs (C), (D), and (F) of this paragraph, any person is exempt from these rules if that person receives, possesses, uses,

transfers, owns, or acquires radioactive material in individual quantities, each of which does not exceed the applicable quantity set forth in subsection (1)(2) of this section.

(B) - (F) (No change.)

(3) Exempt items.

(A) Certain items containing radioactive material.

(i) Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from this chapter if that person receives, possesses, uses, transfers, or acquires the following products:

(I) timepieces, hands, or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:

(-a-) 25 millicuries (mCi) (925 megabecquerels (MBq)) of [(**mCi**) of] tritium per timepiece;

(-b-) - (-g-) (No change.)

(-h-) 1 μ Ci (0.037 MBq) [(**0.037 megabecquerel** (**MBq**))] of radium-226 per timepiece in intact timepieces manufactured prior to January 1, 1986;

(II) static elimination devices which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 μ Ci (18.5 MBq) of polonium-210 per device;

(III) ion generating tubes designed for ionization of air that contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 μ Ci (18.5 MBq) of polonium-210 per device or of a total of not more than 50 mCi (1.85 gigabecquerels (GBq)) of hydrogen-3 (tritium) per device;

(IV) such devices authorized before October 23, 2012, for use under a general license issued in accordance with this section or equivalent regulations of the NRC or an agreement state and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the NRC, any agreement state, or any licensing state;

(V) [(**II**)] lock illuminators containing not more than 15 mCi (555 MBq) of tritium or not more than 2 mCi (74 MBq) of promethium-147 installed in automobile locks. The levels of radiation from each lock illuminator containing promethium-147

will not exceed 1 mrad/hr at 1 cm from any surface when measured through 50 mg/cm² of absorber;

(VI) [(III)] balances of precision containing not more than 1 mCi (37 MBq) of tritium per balance or not more than 0.5 mCi (18.5 MBq) of tritium per balance part manufactured before December 17, 2007;

[(IV) automobile shift quadrants containing not more than 25 mCi of tritium;]

(VII) [(V)] marine compasses containing not more than 750 mCi (27.75 MBq) of tritium gas and other marine navigational instruments containing not more than 250 mCi (9.25 GBq) of tritium gas manufactured before December 17, 2007;

[(VI) thermostat dials and pointers containing not more than 25 mCi of tritium per thermostat;]

(VIII) [(VII)] electron tubes, provided that each tube does not contain more than one of the following specified quantities of radioactive material and that the levels of radiation from each electron tube containing radioactive [byproduct] material do not exceed 1 mrad/hr at 1 cm from any surface when measured through 7 mg/cm² of absorber (For purposes of this clause, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube designed to control electrical currents):

(-a-) 150 mCi (5.55 GBq) of tritium per microwave receiver protector tube or 10 mCi (0.37 GBq) of tritium per any other electron tube;

(-b-) 1 µCi (0.037 MBq) of cobalt-60;

(-c-) 5 µCi (0.185 GBq) of nickel-63;

(-d-) 30 µCi (1.11 GBq) of krypton-85;

(-e-) 5 µCi (0.185 GBq) of cesium-137; or

(-f-) 30 µCi (1.11 GBq) of promethium-147;

(IX) [(VIII)] ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, a source of radioactive material not exceeding:

(-a-) the applicable quantity set forth in subsection (1)(2) of this section or 0.05 µCi (1.85 kilobecquerels (kBq)) of americium-241; and

(-b-) each instrument contains no more than 10 exempt quantities. For purposes of this subclause, an instrument's source(s) shall contain either one type or different types of radionuclides and an individual exempt quantity shall be composed of fractional parts of one or more of the exempt quantities in accordance with subsection (1)(2) of this section, provided that the sum of such fractions shall not exceed unity.

[(IX) spark gap irradiators containing not more than 1 μ Ci of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons per hour; or]

(X) ionization chamber smoke detectors containing not more than 1 μ Ci (37 kBq) **[microcurie (μ Ci)]** of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

(ii) (No change.)

(iii) Any person who desires to apply radioactive material to, or to incorporate radioactive material into, the products exempted in clause (i) of this subparagraph, or who desires to initially transfer for sale or distribution such products containing radioactive material, shall apply for a specific license in accordance with Title 10, CFR, §32.14, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to clause (i) of this subparagraph.

(B) Self-luminous products containing tritium, krypton-85, promethium-147, or radium-226.

(i) Except for persons who manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, and except as provided in clause (iii) of this subparagraph, any person is exempt from this chapter if that person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, produced, **[imported,]** or initially transferred in accordance with a specific license issued by the NRC in accordance with Title 10, CFR, §32.22, which authorizes the initial transfer of the product to persons who are exempt from regulatory requirements. **[The exemption in this subparagraph does not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.]**

(ii) Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under clause (i) of this subparagraph, shall apply for:

(I) a specific license to be issued by the NRC in accordance with Title 10, CFR, §32.22; and

(II) a certificate of registration to be issued by the NRC in accordance with Title 10, CFR, §32.210.

[(ii) Any person is exempt from this chapter if that person receives, possesses, uses, transfers, or owns articles acquired prior to January 1, 1986, each of which contains less than 0.1 μ Ci of radium-226.]

(iii) The exemption in clause (i) of this subparagraph does not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.

(C) Gas and aerosol detectors containing radioactive material.

(i) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from this chapter to the extent **[if]** that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect health, safety, [life] or property. **[from fires and airborne hazards provided that:]**

(I) Detectors **[detectors]** containing radioactive material shall have been manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the NRC in accordance with Title 10, CFR, §32.26. **[, or an agreement state or a licensing state in accordance with §289.252(k) of this title;]**

(II) The **[the]** specific license issued in accordance with Title 10, CFR, §32.26, **[\$289.252 of this title]** authorizes the initial transfer of the product for use to persons who are exempt from regulatory requirements. **[: and]**

(III) This **[this]** exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued in accordance with §289.252 of this title or under comparable provisions to Title 10, CFR, §32.26 authorizing distribution to persons exempt from regulatory requirements.

(IV) Any person who desires to manufacture, process, or produce, gas and aerosol detectors containing radioactive material, or to initially transfer such products for use under this clause, shall apply for:

(-a-) a specific license to be issued by the NRC in accordance with Title 10, CFR, §32.26; and

(-b-) a certificate of registration to be issued by the NRC in accordance with Title 10, CFR, §32.210.

(ii) - (iii) (No change.)

(D) Certain industrial devices. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material designed and manufactured for the purpose of detecting, measuring, gauging

or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere.

(i) Devices containing radioactive material shall have been manufactured, processed, produced, or initially transferred in accordance with a specific license issued under Title 10, CFR, §32.30.

(ii) The specific license issued in accordance with Title 10, CFR, §32.30, authorizes the initial transfer of the device for use under Title 10, CFR, §32.30.

(iii) This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

(iv) Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material for use under this subparagraph, shall apply for:

(I) a license to be issued by the NRC under Title 10, CFR, §32.30; and

(II) a certificate of registration to be issued by the NRC in accordance with Title 10, CFR, §32.210.

(4) (No change.)

(f) General licenses. In addition to the requirements of this section, all general licenses, unless otherwise specified, are subject to the requirements of §289.201 of this title (relating to General Provisions for Radioactive Material), §289.202(ww) and (xx) of this title (relating to Standards for Protection Against Radiation from Radioactive Materials), §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), §289.205 of this title (relating to Hearing and Enforcement Procedures), and §289.257 of this title (relating to Packaging and Transportation of Radioactive Material).

(1) - (3) (No change.)

(4) General licenses for radioactive material other than source material.

(A) - (C) (No change.)

(D) General license for calibration, stabilization, and reference sources.

(i) (No change.)

(ii) The general license in clause (i) of this subparagraph applies only to calibration, stabilization, or reference sources that have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the NRC in accordance with Title 10, CFR, §32.57 or Title 10, CFR, §70.39 or that have been manufactured or initially transferred in accordance with the authorizations contained in a specific license issued to the manufacturer by the agency, any agreement state, or any licensing state, in accordance with licensing requirements equivalent to those contained in Title 10, CFR, §32.57 or Title 10, CFR, §70.39.

(iii) - (iv) (No change.)

(E) - (G) (No change.)

(H) General license for certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.

(i) - (iii) (No change.)

(iv) Any person who receives, acquires, possesses, uses, or transfers radioactive material in a device in accordance with the general license in this subparagraph shall do the following:

(I) - (III) (No change.)

(IV) maintain records for inspection by the agency showing compliance with the requirements of subclauses (II) and (III) of this clause. The records shall show the test results. The records also shall identify the device tested by manufacturer, model and serial number of the device, serial number of the sealed source, and show the dates of performance of and the names of persons performing testing, installation, servicing, and removal from location of installation, of the radioactive material, its shielding or containment. Retention shall be as follows:

(-a-) records for tests for leakage of **[or]** radioactive material required by subclause (II) of this clause shall **[must]** be kept for three years after the next required leak test **[text]** is performed or until the sealed source is transferred or disposed of;

(-b-) records of the test of the on-off mechanism and indicator required by subclause (II) of this clause shall **[must]** be kept for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of; and

(-c-) records of the testing, installation (removal of the manufacturer's lock and initial alignment of the radiation beam), servicing, and removal from location of installation involving the radioactive materials, its shielding or containment required

by subclause (III) of this clause shall be kept for three years from the date of the recorded event or until the device is transferred or disposed of; [.]

(V) - (XIX) (No change.)

(I) - (J) (No change.)

(K) General license for certain items and self-luminous products containing radium-226.

(i) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer radium-226 contained in the following products manufactured prior to November 30, 2007.

(I) - (V) (No change.)

(ii) Any person who acquires, receives, possesses, uses, or transfers radioactive material in accordance with this subparagraph shall do the following.

(I) - (III) (No change.)

(IV) Not export products containing radium-226 except in accordance with or equivalent regulations of the NRC Title 10, CFR, §110.

(V) Dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any federal or state solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued in accordance with this section.

(VI) Respond to written requests from the agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the agency's Radiation Safety Licensing Branch, a written justification for the request.

(g) General license acknowledgements for radioactive material other than source material. In addition to the requirements of this section, all general license acknowledgement holders, unless otherwise specified, are subject to the requirements of §§289.201, 289.202(w) and (xx), 289.204, 289.205, and 289.257 of this title.

(1) Persons possessing a general license for devices in accordance with subsection (f)(4)(H) of this section and being in the possession of radioactive material in devices containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, 3.7 MBq (0.1 mCi) of radium-226, 37 MBq (1 mCi) of americium-241, or any

transuranic (for example, element with atomic number greater than uranium (92)), based on the activity indicated on the label on the device, shall file an application for acknowledgement within 30 days of receipt, acquisition, or possession of such a device. The application shall be on a form prescribed by the agency to include the following information and any other information specifically requested by the agency:

(A) - (F) (No change.)

(G) a completed RC Form 252-1 [**BRC Form 252-1**], Business Information Form and the applicable fee as required by §289.204 of this title.

(2) - (3) (No change.)

(h) - (l) (No change.)